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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,176	03/23/2006	Wolfgang Stachle	MERCK3155	6633
23599 7590 04/12/2010 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
FIERRO, ALICIA				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
04/12/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/573,176

Applicant(s)

STAEHLE ET AL.

Examiner

Alicia L. Fierro

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/8/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11 and 14-38 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 14-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,9-11 and 30-37 is/are rejected.
- 7) ☒ Claim(s) 2,7,8 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-506)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. Claims 1-3, 5-11 and 14-38 are currently pending in the instant application. Claims 6 and 14-29 remain withdrawn for being drawn to a non-elected species/invention.

Continued Examination

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2010 has been entered.

Response to Amendments and Arguments

3. Applicant's arguments and amendments filed July 20, 2009 have been fully considered and entered into the application. All rejections and objections not explicitly maintained herein are withdrawn.
4. Applicants again traverse the restriction requirement, which has already been made **final** for the reasons of record in the office action dated February 20, 2009 and again on December 7, 2009. The Examiner's reasons for properly maintaining the restriction requirement have already been made of record.
5. Applicants argue that claim 6 has been rejoined and examined. However, claim 6 was originally withdrawn for being drawn to non-elected subject matter. Although the scope of the search was extended to include subject matter included in claim 6, no claims are considered for

rejoinder until the linking or generic claim (i.e. claim 1) is found to be allowable. Therefore, claim 6 has not been rejoined for consideration and will be considered for rejoinder upon a finding that claim 1 is in condition for allowance.

6. Applicant's claim amendments overcome the previous rejection made under 35 U.S.C. 102(b). In accordance with MPEP 803.02, the amended claims will be reexamined and the prior art search extended to the extent necessary to determine patentability of the Markush-type claim. The search was extended to a compound of Formula (I) wherein R₂ is R where R is H; R₁ is OR where R is Het; Het is an aromatic heterocycle having 1 N atom (i.e. pyridine), which is monosubstituted by CONHA, where A is methyl; R₃ is H; X is O; Y is phenyl; and n=m=p=1. Because this species was not found allowable, the search was not extended further and the Markush claim was rejected.

Maintained Objections

7. Claims 1-5, 7-11 and 30-38 are objected to for containing non-elected subject matter. This objection can be overcome by submitting an amendment deleting the non-elected subject matter.
8. Claims 2, 8 and 38 are objected to for being dependent upon a rejected base claim, but would not necessarily be allowable if rewritten in independent form.
9. Claim 7 is objected to because when Markush language is used to define a set of claimed compounds, the last two compounds in the list should be separated by the word "and." As such, the word "and" should be inserted between the last compound recited on page 4 of the claims and the first compound on page 5 of the claims.

New Claim Rejections- 35 U.S.C. § 102

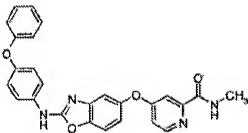
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 3, 5, 9, 10 and 30-37 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Renhowe et al, WO 03/082272, which has a priority filing date back to March 29, 2002.

12. Renhowe et al. teaches the following compound which is identical to the instantly examined species, wherein the substituents are identified in paragraph 8 above. The compound is taught as compound 477 on page 96 of the reference. The compound has the following structure:



The reference also teaches that the compounds can be formulated into pharmaceutical compositions, either alone or in combination with one or more additional anti-cancer agents (see p. 8-9, with specific preferred examples recited on page 9). Therefore, the instant claims drawn

to a pharmaceutical composition, and a pharmaceutical composition comprising the claimed compound and one or more additional active ingredients are also anticipated.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Renhowe et al, WO 03/082272, in view of U.S. Patent No. 6,579,857, published June 17, 2003.

16. Please refer to paragraph 12 above for the relevant teachings of the '272 publication.

17. The '272 reference does not teach a kit of the instantly claimed compound and another active ingredient. However, it is well known in the pharmaceutical art that items can be separated and provided in a kit for the sake of convenience of packaging. The '857 patent states that the unit dose of a particular pharmaceutical agent "is formulated such that the first and

second compositions are packaged together as a kit, but are not in admixture. A kit that includes each therapeutic agent packaged together in dosage form adds convenience for medical practitioners. Separate packaging of the two compositions permits administration by separate routes, at separate times, and/or at separate rates. Separate packaging also permits formulating each composition uniquely" (see column 9, paragraph 4).

18. Thus it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the instantly claimed compound and additional active ingredients taught by the '272 publication in the form of a kit in order to conveniently package the formulations so as to allow for either separate or simultaneous administration with unique formulation of compositions, if desired.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 6:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated

/Golam M. M. Shameem/

Primary Examiner, Art Unit 1626

/Alicia L. Fierro/
Examiner, Art Unit 1626